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TO : Commissioner for Patents
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FROM : Oleg F. Kaplun, Esq. of Fay, Kaplun & Marcin, LLP

DATE : February 26, 2008

SUBJECT : U.S. Patent Appln. Serial No. 10/666,863
for *Fatigue Resistant Medical Devices*
Our Ref.: 10123/00401

NUMBER OF PAGES INCLUDING COVER : 22

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Attorney Docket No. 10123/00401 (03-079US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Walak et al.
Serial No. : 10/666,863
Filing Date : September 17, 2003
For : Fatigue Resistant Medical Devices
Group Art Unit : 1793
Confirmation No. : 8458
Examiner : George P. Wyszomierski

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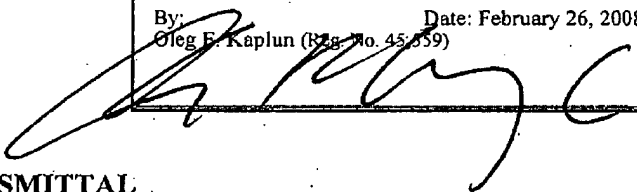
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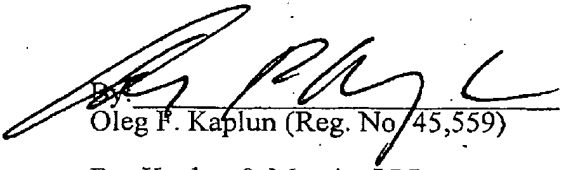
By:  Date: February 26, 2008
Oleg F. Kaplun (Reg. No. 45,559)

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Respectfully submitted,

Dated: February 26, 2008


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Attorney Docket No. 10123/00401 (03-079US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Walak et al.
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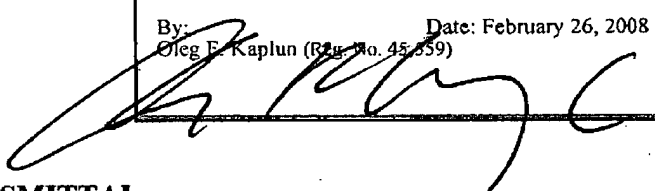
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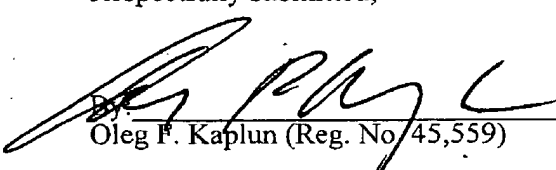
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Respectfully submitted,

Dated: February 26, 2008


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PATENT

Attorney Docket No.: 10123 - 00401

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Walak et al.

Serial No.: 10/666,863

Group Art Unit: 1742

Filed: September 17, 2003

Examiner: George P. Wyszomierski

For: FATIGUE RESISTANT MEDICAL
DEVICESBoard of Patent Appeals and
InterferencesMail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed December 26, 2007, and pursuant to 37 C.F.R. § 41.37, Appellants present this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 23 in the Final Office Action dated August 27, 2007. The appealed claims are set forth in the attached Claims Appendix.

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Group Art Unit: 1742

Attorney Docket No.: 10123 - 00401

1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1 - 23 stand rejected in the Final Office Action. The final rejection of claims 1 - 23 is being appealed.

4. Status of Amendments

In the Advisory Action dated 12/10/07, the Examiner rejected the amendment submitted in the Reply to the Final Office Action submitted on November 27, 2007. (See 12/10/07 Advisory Action, p. 1).

5. Summary of Claimed Subject Matter

The present invention describes, as recited in claim 1, a flexible device comprising a metallic element including high strain portions and lesser strain portions. (See Specification, ¶ [0005]; [0027]; [0035]; Fig. 5). High strain portions of the flexible device are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions. (*Id.*, ¶ [0027]). Claim 1 also recites that the high strain portions comprise a material which is stabilized in a martensite phase. (*Id.*, ¶ [0034]; [0035]; Fig. 5). Claim 1 also recites that the lesser strain portions comprise a material which, under the predetermined operating conditions, is in an austenite phase. (*Id.*, ¶ [0035]; Fig. 5).

Claim 16 recites a medical implant comprising a structural element defining a shape of at least a portion of the implant. (*Id.*, ¶ [0029]). A super-elastic core portion 102 of the element is

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primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase. (*Id.*, ¶ [0021]; [0032]; [0036]; Fig. 6). The medical implant of claim 16 further comprises a fatigue resistant surface portion 108 primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized. (*Id.*, ¶ [0021]; [0032]; [0036]; Fig. 6).

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1 - 8, 15 - 19 and 22 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,514,115 to Frantzen et al. (hereinafter "Frantzen") or over International Published Application No. WO 02/36045 to Walak, (hereinafter referred to as the '045 device).
- II. Whether claims 2, 9 - 13, 20 and 21 are unpatentable under 35 U.S.C. § 103(a) as obvious over Frantzen or the '045 device in view of U.S. Patent No. 5,964,770 to Flomenblit et al. (hereinafter "Flomenblit").
- III. Whether claims 1, 3 - 8, 14 - 19, 22 and 23 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,923,829 to Boyle et al. (hereinafter "Boyle").
- IV. Whether claims 2, 9 - 13, 20 and 21 are unpatentable under 35 U.S.C. § 103(a) as obvious over Boyle in view of Flomenblit.

7. Argument

- I. The Rejection of Claims 1 - 8, 15 - 19 and 22 Under 35 U.S.C. § 103(a) as Obvious Over Frantzen or the '045 Device Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1 - 8, 15 - 19 and 22 were rejected under 35 U.S.C. 103(a) as obvious over Frantzen and the '045 device. (See 8/27/07 Office Action, p. 2). The

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Examiner stated that both Frantzen and the '045 disclose a medical device made of Nitinol alloys including portions that are in a martensitic state and portions in an austenitic state. (*Id.*). The Examiner further noted that Frantzen and the '045 device do not specifically recite the conditions regarding the strain the device is exposed to or the stability of the martensitic phase when deployed in the body but that it is a reasonable assumption that these parameters would be the same or nearly the same in the Frantzen and '045 devices and has thus declared a prima facie case of obviousness. (*Id.*). In the Advisory Action dated December 10, 2007, the Examiner further stated that it is not possible to determine what portions of a given material are subjected to a higher or lesser strain. (See 12/10/07 Advisory Action, p. 2).

B. Neither Frantzen nor the '045 Device Shows or Suggests High Strain Portions and Lesser Strain Portions as Recited in Claim 1 or a Super-elastic Core Portion and a Fatigue-resistant portion as Recited in Claim 16

Claim 1 recites a flexible device comprising "a metallic element including *high strain portions* and *lesser strain portions*, wherein the *high strain portions* are to be subjected to levels of strain during use increased with respect to strain levels in the *lesser strain portions*, the high strain portions comprising a material which is stabilized in a martensite phase and the lesser strain portions comprise a material which, under the predetermined operating conditions, is in an austenite phase." (Emphasis added).

Appellants submit that Frantzen fails to teach or suggest the placement of the martensite stabilized material in "high strain portions" and a material which, under the predetermined operating conditions, is in an austenite phase in lesser strain portions. Claim 1 specifically states that the high strain portions are subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions. In contrast, Frantzen describes evenly distributing martensite and austenite portions of the housing irrespective of levels of strain to which these

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portions of the device will be subjected. (See Frantzen, col. 7, ll. 33 - 38; Fig. 4, 7).

Specifically, Frantzen purports to describe a flexible elongated tubular housing for removing tissue or other material from a body lumen or cavity, such as an atherectomy catheter. (See Frantzen, col. 2, ll. 27 - 36; Fig. 4). In one embodiment, the Frantzen device is provided with "a plurality of heat treated cylindrically shaped tubular sections 40 to provide improved housing flexibility." (See Frantzen, col. 7, ll. 3 - 6). In another embodiment, the housing of the Frantzen device is provided with "an elongated strip 50 in the martensite phase which is transformable to an austenite phase with a straight memory by the application of heat to raise the temperature of the strip to above the A_s temperature." (See Frantzen, col. 7, ll. 33 - 38; Fig. 7). It is noted that, in both of these embodiments, Frantzen discloses the placement of martensite portions of Nitinol evenly distributed along the length of the housing. (*Id.* at Figs. 4, 7). Nowhere does Frantzen either show or suggest the placement of the martensite and austenite portions in any way related to the strain which is anticipated to be exerted on a portion of the housing.

The Examiner has further stated that it is not possible to determine what portion(s) of a given material will be subjected to high strain and lesser strain at some indefinite point in the future. (See 12/10/07 Advisory Action, p. 2). However, it is noted that high strain portions of an element are easily locatable via deformation analysis as is extremely well known to those skilled in the art. The design of nearly any product from enormous bridges to implantable medical devices has been subjected to this analysis for an exceedingly long time and is a standard practice throughout the world. The Specification states:

When a strain is applied to the alloy element, the element is deformed to the state B in which the alloy element contains large areas of strain-induced martensite. *These areas occur primarily at locations at which the highest levels of strain are induced and result in severe deformation that may be unrecoverable in an element of non-shape memory normal material.*" (See Specification, ¶ [0022]).

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It is submitted that areas of high strain may be located in a medical implant or any other device by performing an analysis to determine which areas of the implant have undergone deformation. This information can then be used to place martensite or austenite phase material accordingly. As noted above, Frantzen neither teaches nor suggests the selective placement of martensite and austenite portions based on an amount of strain applied to a particular area.

It is respectfully submitted that the Examiner's assumptions about the cited reference are completely unsupported by the reference and that this assumption constitutes an improper hindsight reconstruction of the invention. For these reasons, it is respectfully submitted that a prima facie obviousness rejection has not been established with respect to claim 1 and that claim 1 is allowable over Frantzen. Because claims 2 - 8 and 15 depend from and, therefore, are allowable.

Claim 16 recites a medical implant comprising "*a super-elastic core portion of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a fatigue resistant surface portion primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized.*" (Emphasis added).

The only disclosure Frantzen makes with respect to the placement of austenitic phase and martensitic phase portion is noted in Figures 4 - 10. (See Frantzen, col. 7, li. 3 - 54; Figs. 4 - 10). In none of these disclosures does Frantzen teach a "super-elastic core portion" separate from a "fatigue resistant surface portion," as recited in claim 16. Rather, Frantzen only seeks to provide austenitic or martensitic portion along selected portions of the *surface* of each of the embodiments taught therein. (*Id.*) Furthermore, it is noted that it would not be possible to modify the Frantzen device to include a "super-elastic core portion," as recited in claim 16 as the housing 17 of Frantzen is intended to be hollow to slidably receive a cutting blade therein. (See Frantzen, col. 5, li. 63 to col. 6, li. 9; Figs. 1 - 10).

Accordingly, it is respectfully submitted that one skilled in the art would not have been motivated to have modified the Frantzen device to employ a "super-elastic core portion" with a "fatigue resistant surface portion," as recited in claim 16 and that claim 16 and its dependent

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claims 17 - 19 and 22 are allowable over Frantzen.

As with Frantzen, the '045 patent makes no mention of strain as a deciding factor in the placement of superelastic portions and it is submitted that any suggestion that the locations of these plastically deformable portions is based on the location of higher and lesser strain portions is unsupported by the '045 patent. Specifically, the '045 patent purports to describe an endoluminal device such as a stent comprising at least one superelastic section and at least one plastically deformable section. (*See* '045, p. 3, ll. 1 - 2). Various embodiments of the '045 device include superelastic portions disposed at various longitudinal lengths of the device, the placement of the superelastic portions being designed to allow the device to "be tailored to conform to the anatomy of a lumen in which it is deployed by deforming the plastically deformable section of the device without changing the characteristics of the superelastic section of the device." (*See Id.*, p. 17, ll. 4 - 14; Figs. 1, 4A - 4F, 7A - 7F). It is therefore noted that the placement of the plastically deformable (martensite) portions along the '045 device is dictated to allow for an even distribution of flexibility along the length of the device and is in no way linked to the location of high and lesser strain portions, as recited in claim 1.

It is respectfully submitted that the Examiner's assumptions about the '045 patent are completely unsupported by the reference and that this assumption constitutes an improper hindsight reconstruction of the invention. For these reasons, it is respectfully submitted that a prima facie obviousness rejection has not been established with respect to claim 1 and that claim 1 and its dependent claims 2 - 8 and 15 are allowable over the '045 patent.

Furthermore, the '045 device fails to teach or suggest a medical device comprising a "super-elastic core portion" separate from a "fatigue resistant surface portion", as recited in claim 16. Rather, the '045 device is directed to providing super-elastic portions and fatigue resistance portions on a surface thereof. (*See* '045, p. 3, ll. 6 - 11; Figs. 1, 4A - 4C, 5A - 5C, 6). Specifically, the '045 device teaches the placement of super-elastic and plastically deformable sections in an alternating longitudinal pattern, so as to allow for the radial expansion of the device. (*Id.*, *See Also*, p. 9, ll. 11 - 22). The '045 does not teach or suggest a fatigue-resistant

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surface portion. Rather, employing a fatigue-resistant surface portion in the '045 device would be detrimental thereto as it would hinder the radial expansion of the device. (See '045, p. 2, li. 31 to p. 3, li. 11).

Accordingly, Appellants respectfully submit that the '045 device does not teach or suggest a medical implant comprising "*a super-elastic core portion* of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and *a fatigue resistant surface portion* primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized," as recited in claim 16 and that claim 16 and its dependent claims 17 - 19 and 22 are allowable over the '045 device for at least this reason.

II. The Rejection of Claims 2, 9-13, 20 and 21 Under 35 U.S.C. § 103(a) as Obvious over the Frantzen or the '045 Device in view of Flomenblit Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 2, 9 - 13, 20 and 21 were rejected under 35 U.S.C. 103(a) as unpatentable over the Frantzen or the '045 device in view of Flomenblit. (See 8/27/07 Office Action, p. 3).

B. Neither Frantzen nor the '045 Device, nor Flomenblit either Shows or Suggests Either High and Lesser Strain Portions as Recited in Claim 1 or a Super-elastic Core as Recited in Claim 16

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Frantzen or the '045 device. Claims 2 and 9 - 13 depend from and therefore include all the limitations of independent claim 1. As discussed above, neither Frantzen nor the '045 device teach or suggest the limitations of independent claim 1 and claim 1 is allowable over Frantzen and the '045 device. Flomenblit fails to cure the deficiencies of Frantzen and the '045

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device noted above. Accordingly, because claims 2 and 9 - 13 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable for the same reasons. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claims 2 and 9 - 13.

Claim 16 has also been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Frantzen or the '045 device. Claims 20 and 21 depend from and therefore include all the limitations of independent claim 16. As discussed above, neither Frantzen nor the '045 device teach or suggest the limitations of independent claim 16 and claim 16 is allowable over Frantzen and the '045 device. Flomenblit fails to cure the deficiencies of Frantzen and the '045 device note above. Accordingly, it is respectfully submitted that claims 20 and 21 which depend from and, therefore, include all of the limitations of independent claim 16, are allowable for the same reasons stated above in regard to claim 16. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claims 20 and 21

III. The Rejection of Claims 1, 3 - 8, 14 - 19, 22 and 23 Under 35 U.S.C. § 103(a) as Obvious over Boyle Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 3 - 8, 14 - 19, 22 and 23 were rejected under 35 U.S.C. 103(a) as obvious over Boyle. (See 8/27/07 Office Action, pp. 3 - 4). The Examiner stated that Boyle also discloses an implantable medical device made of Nitinol, portions of which are in an austenitic phase and portions in a martensitic phase. (*Id.*)

B. Boyle does not Disclose High Strain Portions and Lesser Strain Portions as Recited in Claim 1

Boyle purports to describe endoluminal devices "having regions that are either plastically deformable or are sufficiently martensitic to behave pseudoplastically in vivo, and regions that

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are elastically deformable or sufficiently austenitic to behave pseudoelastically or superelastically in vivo.” (See Boyle, col. 4, ll. 16 - 21). The only descriptions in Boyle in regard to placement of the martensitic and austenitic portions pertain to placements allowing for a maximization of plastic deformability. (See Boyle, col. 4, ll. 30 - 45). Boyle does not disclose or suggest the placement of martensitic portions based on an amount of strain to which a particular portion of the device will be subjected during use. As noted above with regard to the 35 U.S.C. § 103(a) rejection of claim 1 over Frantzen or the ‘045 device, the Specification discloses a means for determining high stress portions of a device which is in any case known to those skilled in the art. (See Specification, ¶ [0022]). Accordingly, it is noted that Boyle does not teach “a metallic element including *high strain portions* and *lesser strain portions*, wherein *the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions*, the high strain portions comprising a material which is *stabilized in a martensite phase* and the lesser strain portions comprise a material which, *under the predetermined operating conditions, is in an austenite phase*,” as recited in claim 1. It is respectfully submitted that Boyle does not teach or suggest the limitations of claim 1 and that claim 1 and its dependent claims 3 - 8 and 14 - 15 are allowable.

Claim 16 recites “a *super-elastic lesser strain core portion* of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a *fatigue resistant high strain surface portion* primarily formed of Nitinol which, at body temperature, is substantially martensite phase stabilized, *wherein the high strain portion is to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portion*.” As noted above with respect to the 35 U.S.C. § 103(a) rejection of claim 16 under Frantzen and the ‘045 device, claim 16 specifically recites that a core portion of a medical device is formed of a super-elastic Nitinol material while a surface portion thereof is formed of a fatigue resistant martensitic material. In contrast, Boyle does not teach or suggest a device wherein a core portion is super-elastic and a surface portion is a fatigue resistant martensitic material. Rather, the only disclosure Boyle makes with regard to the placement of austenitic and martensitic portions

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denotes that they be placed in an pattern on a surface of the endoluminal stent 10. (See Boyle, col. 7, ll. 15 - 37; Figs. 1 - 3). Specifically, Boyle states the importance of having a first hinge members 14 formed of a sufficiently austenitic material to allow for diametrical expansion of the ring members 11 as well as second hinge members 20 formed of a sufficiently martensitic material to allow for longitudinal expansion of the device. (*Id.*, col. 7, ll. 38 - 54; Figs. 1 - 3). It is submitted that Boyle does not disclose or suggest a surface portion formed of a martensitic material or a super-elastic core portion therein. Furthermore, it is submitted that modifying the Boyle device to overcome the limitations of claim 16 would be detrimental thereto. Specifically, Boyle explicitly recites the importance of having both radial and longitudinal expansion and flexibility therein. (*Id.*, col. 8, ll. 22 - 28). Modifying the Boyle device to include a martensitic surface portion would reduce such flexibility. It is therefore submitted that Boyle fails to teach or suggest the limitations of claim 16 and claim 16 is allowable over Boyle. Because claims 17 - 19, 22 and 23 depend from, and therefore include all of the limitations of claim 16, it is submitted that these claims are also allowable.

IV. The Rejection of Claims 2, 9 - 13, 20 and 21 Under 35 U.S.C. § 103(a) as Obvious over Boyle in view of Flomenblit Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 2, 9 - 13, 20 and 21 were rejected under 35 U.S.C. 103(a) as obvious over Boyle in view of Flomenblit. (See 8/27/07 Office Action, p. 4).

B. Neither Boyle nor Flomenblit Discloses or Suggests Either Higher and Lesser Strain Portions as Recited in Claim 1 or a Super-elastic Core Portion as Recited in Claim 16

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 103(a)

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rejection under Boyle. Claims 2 and 9 - 13 depend from and therefore include all the limitations of independent claim 1. As discussed above, Boyle does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Boyle. Flomenblit does not cure the deficiencies of Boyle noted above. Accordingly, it is respectfully submitted that claims 2 and 9 - 13 are allowable for the same reasons stated in regard to claim 1.

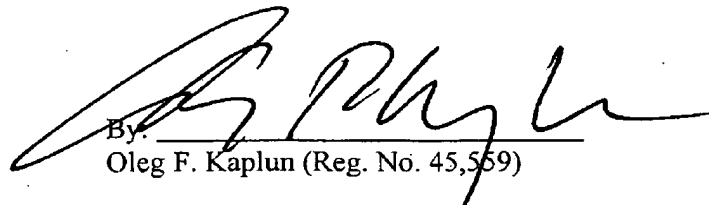
Claim 16 has been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Boyle. Claims 20 and 21 depend from and therefore include all the limitations of independent claim 16. As discussed above, Boyle does not teach or suggest the limitations of independent claim 16 and claim 16 is therefore allowable over Boyle. Flomenblit does not cure the deficiencies of Boyle noted above. Accordingly, it is respectfully submitted that claims 20 and 21 are allowable for the same reasons stated in regard to claim 16.

8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a) and indicate that claims 1 - 23 are allowable.

Respectfully submitted,

Date: February 26, 2008

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- 12 -

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Group Art Unit: 1742
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CLAIMS APPENDIX

1. (Previously Presented) A flexible device comprising a metallic element including high strain portions and lesser strain portions, wherein the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions, the high strain portions comprising a material which is stabilized in a martensite phase and the lesser strain portions comprise a material which, under the predetermined operating conditions, is in an austenite phase.
2. (Original) The device according to claim 1, further comprising a transition portion disposed between and providing a transition between the high strain and lesser strain portions.
3. (Original) The device according to claim 1, wherein the element is formed substantially of Nitinol.
4. (Original) The device according to claim 1, wherein an austenite transition temperature of the high strain portion is greater than an austenite transition temperature of the lesser portion.
5. (Original) The device according to claim 1, wherein the device is a medical device to be inserted within a living body.
6. (Original) The device according to claim 5, wherein an austenite transition temperature of the high strain portion is greater than a body temperature of the living body into which the device is to be inserted.
7. (Original) The device according to claim 6, wherein the austenite transition temperature of the

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high strain portion is greater than 37 C .

8. (Original) The device according to claim 1, wherein the high strain portion is a plastically deformed surface portion of the element.

9. (Original) The device according to claim 1, wherein the high strain portion is a surface portion of the element which has been treated with an ion implantation process.

10. (Original) The device according to claim 9, wherein the high strain portion is a surface portion of the element which has been treated with an ion implantation process.

11. (Original) The device according to claim 9, wherein the high strain portion includes at least a portion of a surface of the element into which ions of one of Pd, Pt, Au, Cu, Hf, Zr, Nb, Ta and Ti have been implanted.

12. (Original) The device according to claim 1, wherein the high strain portion is a doped surface portion of the element.

13. (Original) The device according to claim 12, wherein the high strain portion includes at least a portion of a surface of the element in which one of Pd, Pt, Au, Cu, Hf, Zr, Nb, Ta and Ti has been added.

14. (Original) The device according to claim 1, wherein a titanium concentration in the high strain portion is greater than a titanium concentration in the lesser strain portion.

15. (Original) The device according to claim 8, wherein the plastically deformed portion is one of a shot peened surface and an extruded surface of the element.

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16. (Previously Presented) A medical implant comprising a structural element defining a shape of at least a portion of the implant, a super-elastic core portion of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a fatigue resistant surface portion primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized.

17. (Original) The implant according to claim 16, wherein the element is one of a wire, tubing and a sheet.

18. (Original) The implant according to claim 16, wherein at least a portion of a surface of the element is plastically deformed.

19. (Original) The implant according to claim 18, wherein the plastically deformed portion of the surface is one of shot peened and low temperature extruded.

20. (Original) The implant according to claim 16, wherein the fatigue resistant surface portion is treated with an ion implantation process.

21. (Original) The implant according to claim 16, wherein the fatigue resistant surface portion is doped with one of Pd, Pt, Au, Cu, Hf, Zr, Nb, Ta and Ti.

22. (Original) The implant according to claim 16, wherein the fatigue resistant surface portion is a cladding layer formed around the super-elastic core portion.

23. (Original) The implant according to claim 19, wherein the fatigue resistant surface portion has a ratio of nickel and titanium modified with respect to that of the super-elastic core portion.

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24. (Withdrawn) A method of forming an element of a medical device comprising the steps of:

forming an element of the device of Nitinol;

impressing a memorized shape on the element, wherein the memorized shape is a shape the element is to assume when in an operational configuration; and

treating a high strain portion of the element so that the high strain portion is substantially Martensite phase stabilized under expected operating conditions of the device, wherein untreated portions of the element are in a substantially austenitic phase under the expected operating conditions.

25. (Withdrawn) The method of claim 24, wherein the high strain portion is substantially Martensite phase stabilized by plastic deformation.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.